In the Supreme Court of the United States

OCTOBER TERM, 1965

No. 824

ABBOTT LABORATORIES, ET AL., PETITIONERS,

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a–9a) is reported at 352 F. 2d 286. The opinion of the district court (Pet. App. 12a–27a) is reported at 228 F. Supp. 855.

JURISDICTION

The judgments of the court of appeals were entered on November 1, 1965 (Pet. App. 28a–30a). The petition for a writ of certiorari was filed on December 15, 1965. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

207-060—66

QUESTIONS PRESENTED

1. Whether interpretive regulations issued by respondents with respect to the generic-name requirements of 1962 amendments to the Federal Food, Drug and Cosmetic Act may be challenged by petitioners in an action under the Declaratory Judgment Act or the Administrative Procedure Act.

2. Whether corporations doing business in a State but not incorporated therein may bring a civil suit in that State against federal officers under 28 U.S.C. 1391(e)(4).

STATUTES AND REGULATION INVOLVED

The relevant statutes and regulation appear in the Appendix, pp. 10–14, *infra*.

STATEMENT

Section 502(e)(1)(B) of the Federal Food, Drug and Cosmetic Act, enacted as part of the Drug Amendments of 1962, 76 Stat. 780, 790, requires "the established name" of any prescription drug to be "printed prominently" on any label and on any labeling in which any proprietary name of the drug appears "in type at least half as large as that used thereon for any proprietary name or designation for such drug" (p. 12, *infra*).[1] On February 14, 1963, the Commissioner of Food and Drugs, acting pursuant to rule-making authority of the Act, 21 U.S.C. 371(a), and under Section 4 of the Administrative

[1] Section 502(n) requires the established name to appear in any advertisement for a prescription drug in type at least half as large as that used for any trade or brand name. 76 Stat. 791–792 (p. 12, *infra*).

Procedure Act, 5 U.S.C. 1003, announced proposed regulations for the enforcement of this provision. The regulations provided that the generic name of a prescription drug accompany each appearance of any trade name on labels, labeling and advertising. 28 Fed. Reg. 1448. The Pharmaceutical Manufacturers Association (PMA) and several of its member firms offered written comments, challenging the proposed interpretation as legally erroneous. They asserted that the "every time" use of the established name would adversely affect the readability of the promotional material and asked that the interpretation not be adopted. No requests for exemption on the basis of a showing of impracticality were made. The regulations were adopted in final form on June 20, 1963. 28 Fed. Reg. 6375; App. pp. 13–14, *infra*.

In September 1963, the PMA and 37 of its 140 member companies instituted this action in the District Court for the District of Delaware under the Declaratory Judgment Act and the Administrative Procedure Act seeking a declaration that the "every time" interpretation embodied in the regulations was unwarranted and requesting an injunction against its enforcement. On cross-motions for summary judgment, the district court ruled that venue was improper for 26 corporate plaintiffs which were not incorporated in Delaware, but it otherwise granted the relief sought. The court held that the statute did not allow the interpretation made by the regulations and that the existence of the regulations posed a threat of harm to petitioners. It enjoined respondents from enforcing the interpretation embodied in the regula-

tions (Pet. App. 12a–27a). The court of appeals reversed on the ground that review of the interpretive regulation was not available at this juncture under the Declaratory Judgments Act or the Administrative Procedure Act (Pet. App. 1a–9a).

ARGUMENT

This case involves an attempt by petitioners to obtain a judicial determination regarding the validity of a regulation issued by respondents reflecting their understanding of a recently enacted statute. The court of appeals held that review of this "interpretive" regulation was not available at the present juncture (1) "in view of the policy of Congress limiting prior judicial review of administrative actions under [the Food, Drug and Cosmetics] Act to specific sections, not including the ones in question" and (2) "in view of the absence of an 'actual case or controversy' required for justiciability under the Declaratory Judgment Act" (Pet. App. 9a). Although we agree that there may be substance to petitioners' contention that the second reason given by the court of appeals is inconsistent with *Frozen Food Express* v. *United States*, 351 U.S. 40, we believe that the decision below is correct on the first ground—*i.e.*, that the provisions regarding judicial review in the Food, Drug and Cosmetic Act demonstrate Congress' intention to limit the instances in which the agency may be forced to defend its issued regulations prior to its enforcement of them. In light of the other available procedures by which the regulation's validity may be tested and the absence of any likelihood of criminal prosecution prior to a definitive decision regarding the regulation,

we believe there is no need for this Court presently to review the decision of the court of appeals.

1. As this Court observed in *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 600-601, Congress was "highly selective" in authorizing judicial review of administrative action under the Food, Drug, and Cosmetic Act. Section 701 of the Act, 21 U.S.C. 371, confers on the Secretary of Health, Education, and Welfare the authority to promulgate regulations, as do many other substantive provisions of the law. See, *e.g.*, 21 U.S.C. 352(n). Subsection (f) provides for judicial review only of "any order under subsection (e) of this section," and subsection (e) specifically enumerates seven kinds of regulations which are subject to the procedures prescribed therein (pp. 12-13, *infra*). The explicit listing of the enumerated regulations warrants the inference that Congress intended that no other regulations be reviewable before they were carried into effect by the agency.

The Act is enforced by administrative processes such as new-drug clearance or antibiotic certification as well as by injunction, seizure and criminal prosecution. Consequently, there are many avenues by which respondents' interpretation of the statute may be tested. Moreover, petitioners may seek exemption from the "every time" requirement under the proviso in Section 502(e)(1)(B). It is not the policy of the Food and Drug Administration to proceed in the first instance by way of criminal sanctions when, as the district court's decision discloses to be true here, its reading of the statute is subject to differences of opinion, and the Department of Justice will

not attempt to invoke criminal liability under the regulation at issue until its validity has been authoritatively established in administrative proceedings subject to judicial review or in civil proceedings. Consequently, there is no danger that fear of criminal prosecution will deter a test of the regulation's validity.[1]

Since enforcement of a regulation such as this one immediately presents a vehicle for judicial review of its validity, it was reasonable for Congress to make such a regulation non-reviewable at the present juncture. When it is actually enforced by refusal

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[1] Although the underlying merits of the controversy are not presently before the Court, we submit that the regulation, on its face, is a reasonable construction of the statute and is supported by its legislative history. The word "any" appears in Section 502(e)(1)(B) three times, and it is most reasonable to read it as meaning "all." See p. 12, *infra*. Thus read, the concluding phrase—"for any proprietary name or designation for such drug or ingredient"—means that the generic name must accompany *all* appearances of the brand-name on the label. This construction is supported by the legislative history of the 1962 amendments. The Senate Judiciary Committee's report stated with regard to this provision (Sen. Rep. No. 1744, pt. 2, 87th Cong., 2d Sess., p. 8):

> The substitute committee amendment * * * would require that the label bear the "established" name of the drug and the established name of each active ingredient * * *. It would also require that *on labels and on any labeling, wherever a trade or brand name is used, the established name*, as defined in this section, *must be shown in type at least one-half as large as that used for the trade or brand name.* [Emphasis added.]

The Conference Committee adopted the Senate version (H. Rep. No. 2426, 87th Cong., 2d Sess., pp. 23-24), and Senator Kefauver, the leading sponsor of the legislation, explained that it meant precisely what respondents' regulation says (108 Cong. Rec. 22039).

to clear a new drug which is, in respondents' view, misbranded, or by injunction or seizure, the reviewing court will have before it a concrete situation involving specific labeling. Petitioners' complaint alleged, *inter alia*, that the regulation was invalid because it rendered drug labeling "confusing and repetition and * * * difficult * * * to read," and this contention could obviously be weighed more intelligently in the context of a specific enforcement proceeding.

2. This Court held in *Frozen Food Express* v. *United States*, 351 U.S. 40, that a challenge to an interpretive order issued after a plenary administrative hearing presented a justiciable controversy which could be litigated in a reviewing court even before administrative enforcement. The present case turns, however, not only on justiciability but also on whether review at this juncture is authorized by statute. The governing statute in the *Frozen Food Express* case made "any order of the Interstate Commerce Commission" reviewable (28 U.S.C. 1336(a)) and did not, as does the Food, Drug and Cosmetic Act, narrowly define the kinds of regulations subject to judicial review. Similarly, in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, a rule of the Federal Communications Commission was deemed reviewable in "light of the legislation allowing review of the Commission's actions." 351 U.S. at 200.[8]

[8] *Columbia Broadcasting System* v. *United States*, 316 U.S. 407, concerned a rule which had an immediate effect on station licensees who, if they followed the agency's regulation, were required to cancel existing affiliation agreements before the time at which the agency would implement its ruling.

Nor is review available here under the Administrative Procedure Act or the Declaratory Judgment Act. This is not a case, as was *Rusk* v. *Cort*, 369 U.S. 367, in which denial of relief under these statutes would compel the allegedly aggrieved party to undergo considerable hardship in order to obtain review.[4] Nor is it a case like *Leedom* v. *Kyne*, 358 U.S. 184, where this Court held an administrative agency's order reviewable notwithstanding the absence of any specific review authorization in the governing statute because "'absence of jurisdiction of the federal courts' would mean 'a sacrifice or obliteration of a right which Congress' has given" (358 U.S. at 190). In the present case an entire industry is seeking an adjudication regarding the intended enforcement of the Act by those who have the duty of enforcing it. Review of the validity of such enforcement will be available, with minimal hardship to petitioners, when enforcement is begun. The Administrative Procedure Act was not intended to authorize the anticipatory review sought here. See Attorney General's Manual on the Administrative Procedure Act, pp. 94–105.

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[4] In *Rusk* v. *Cort*, *supra*, this Court, though noting that the Administrative Procedure Act and the Declaratory Judgment Act appeared "clearly to permit an action such as was brought" in that case (369 U.S. at 372), went on to consider whether the statutorily prescribed procedures in the Immigration and Nationality Act were exclusive. The Court concluded that it was unlikely that Congress intended "that a native of this country living abroad must travel thousands of miles, be arrested, and go to jail in order to attack an administrative finding that he is not a citizen of the United States." 369 U.S. at 375.

3. Petitioners' second question is of no practical importance in this case. If, as the court of appeals held, the regulations are not presently reviewable, there is no court where this action could properly have been brought. On the other hand, if the decision of the district court is correct, that court's judgment will inure to the benefit of all the members of PMA, including those who did not join in the suit. And, in any event, if enforcement of the regulation is enjoined, there is no real likelihood that it will be enforced against companies who were not nominal plaintiffs in the suit.

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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APPENDIX

The Federal Declaratory Judgment Act, 28 U.S.C. 2201, provides, in pertinent part:

Creation of remedy.

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, provides in pertinent part:

SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

28 U.S.C. 1391(e) provides, in pertinent part:

§ 1391. Venue generally.

* * * * *

(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action.

Section 502 of the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 790, 21 U.S.C. 352, provides, in pertinent part:

SEC. 502. A drug or device shall be deemed to be misbranded—* * *

(e) * * *

(1) If it is a drug, unless * * *

(B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling in which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause * * * (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

* * * * * *

(n) In the case of any prescription drug * * * the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula * * *, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) * * *

Section 701 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 371, provides, in pertinent part:

SEC. 701. Regulations and hearings.

(a) Authority to promulgate regulations.

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * * *

(e) Procedure for establishment.

(1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352 (d) or (h) of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary, * * *

* * * * *

(f) Review of order.

(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. * * *

* * * * *

21 C.F.R. 1.104 provides, in pertinent part:

* * * * *

(g)(1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

(2) The established name shall be printed in letters that are at least half as large as the

letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

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